

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Subpart A--General Provisions

Sec. 7.3 Definitions.

- (a) Agency means the Food and Drug Administration.
- (b) Citation or cite means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.
- (c) Respondent means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.
- (d) Responsible individual includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.
- (e) [Reserved]
- (f) Product means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. Product does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.
- (g) Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.
- (h) Correction means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.
- (i) Recalling firm means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.
- (j) Market withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine

equipment adjustments and repairs, etc.

(k) Stock recovery means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

(l) Recall strategy means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

(m) Recall classification means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

(1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

(2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

(3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

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(n) Consignee means anyone who received, purchased, or used the product being recalled.

[42 FR 15567, Mar. 22, 1977, as amended at 43 FR 26218, June 16, 1978; 44 FR 12167, Mar. 6, 1979]

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Sec. 7.40 Recall policy.

Source: 43 FR 26218, June 16, 1978, unless otherwise noted.

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and Secs. 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

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Sec. 7.41 Health hazard evaluation and recall classification.

(a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

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Sec. 7.42 Recall strategy.

(a) General. (1) A recall strategy that takes into account the

following factors will be developed by the agency for a Food and Drug Administration-requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

- (i) Results of health hazard evaluation.
- (ii) Ease in identifying the product.
- (iii) Degree to which the product's deficiency is obvious to the consumer or user.
- (iv) Degree to which the product remains unused in the market-place.
- (v) Continued availability of essential products.

(2) The Food and Drug Administration will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

(b) Elements of a recall strategy. A recall strategy will address the following elements regarding the conduct of the recall:

(1) Depth of recall. Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

- (i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or
- (ii) Retail level, including any intermediate wholesale level; or
- (iii) Wholesale level.

(2) Public warning. The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:

- (i) General public warning through the general news media, either national or local as appropriate, or
- (ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

(3) Effectiveness checks. The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled "Methods for Conducting Recall Effectiveness Checks" that describes the use of these different methods is available upon

request from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the Food and Drug Administration will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

- (i) Level A--100 percent of the total number of consignees to be contacted;
- (ii) Level B--Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;
- (iii) Level C--10 percent of the total number of consignees to be contacted;
- (iv) Level D--2 percent of the total number of consignees to be contacted; or
- (v) Level E--No effectiveness checks.

[43 FR 26218, June 16, 1978, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14363, Mar. 28, 1994]

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Sec. 7.45 Food and Drug Administration-requested recall.

(a) The Commissioner of Food and Drugs or his designee under Sec. 5.20 of this chapter may request a firm to initiate a recall when the following determinations have been made:

- (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.
- (2) That the firm has not initiated a recall of the product.
- (3) That an agency action is necessary to protect the public health and welfare.

(b) The Commissioner or his designee will notify the firm of this

determination and of the need to begin immediately a recall of the product. Such notification will be by letter or telegram to a responsible official of the firm, but may be preceded by oral communication or by a visit from an authorized representative of the local Food and Drug Administration district office, with formal, written confirmation from the Commissioner or his designee afterward. The notification will specify the violation, the health hazard classification of the violative product, the recall strategy, and other appropriate instructions for conducting the recall.

(c) Upon receipt of a request to recall, the firm may be asked to provide the Food and Drug Administration any or all of the information listed in Sec. 7.46(a). The firm, upon agreeing to the recall request, may also provide other information relevant to the agency's determination of the need for the recall or how the recall should be conducted.

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Sec. 7.46 Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in Sec. 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:

- (1) Identity of the product involved.
- (2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
- (3) Evaluation of the risk associated with the deficiency or possible deficiency.
- (4) Total amount of such products produced and/or the timespan of

the production.

(5) Total amount of such products estimated to be in distribution channels.

(6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.

(7) A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.

(8) Proposed strategy for conducting the recall.

(9) Name and telephone number of the firm official who should be contacted concerning the recall.

(b) The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.

(c) A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. The firm's action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.

(d) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with the appropriate Food and Drug Administration district office when the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse

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reactions regarding the product, that the product is deficient in some respect. In such cases, the Food and Drug Administration will assist the firm in determining the exact nature of the problem.

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Sec. 7.49 Recall communications.

(a) General. A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

- (1) That the product in question is subject to a recall.
- (2) That further distribution or use of any remaining product should cease immediately.
- (3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.
- (4) Instructions regarding what to do with the product.

(b) Implementation. A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "drug [or food, biologic, etc.] recall [or correction]". The letter and the envelope should be also marked: "urgent" for class I and class II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

(c) Contents. (1) A recall communication should be written in accordance with the following guidelines:

- (i) Be brief and to the point;
 - (ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;
 - (iii) Explain concisely the reason for the recall and the hazard involved, if any;
 - (iv) Provide specific instructions on what should be done with respect to the recalled products; and
 - (v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.
- (2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, followup communications should be sent to those who fail to respond to the initial recall communication.

(d) Responsibility of recipient. Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

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Sec. 7.50 Public notification of recall.

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also includes other Food and Drug Administration regulatory actions, e.g., seizures that were effected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

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Sec. 7.53 Recall status reports.

(a) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office

so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 weeks.

(b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

(1) Number of consignees notified of the recall, and date and method of notification.

(2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.

(3) Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administration).

(4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.

(5) Number and results of effectiveness checks that were made.

(6) Estimated time frames for completion of the recall.

(c) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

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Sec. 7.55 Termination of a recall.

(a) A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.

(b) A recalling firm may request termination of its recall by

submitting a written request to the appropriate Food and Drug Administration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

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Sec. 7.59 General industry guidance.

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. Notwithstanding similar specific requirements for certain products in other parts of this chapter, the following is provided by the Food and Drug Administration as guidance for a firm's consideration:

- (a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with Secs. 7.40 through 7.49, 7.53, and 7.55.
- (b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.
- (c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.